U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  LEST OF REFERENCES CITED BY APPLICANT(S) ((Use secretal shorts) il rescension)  U.S. PATENT DOCUMENTS  COMMER  DOCUMENT  DATE  COMMER  COLOREST  DATE  COUNTY  COLOREST  DOCUMENTS SUBMITTED UNDER MPEP § 724  CONTROLLABOR OF PETTHONS  EXPERT Report of Cheryl D. Blume, Ph.D. (January 27, 2004)  Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Sergio Fazio Regarding U.S. Patent No. 6,676,967 (August 17, 2004)  Expert Report of Dr. W. Martens Regarding U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 6,676,967 (August 18, 2004)  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 6,676,967 (August 18, 2004)  - Subject to Protective Order	FORM PTO 1448 (modified)			ATTY DOCKET NO. APPLICATION NO.				
PATISIT AND TRADEMAND OFFICE  LIST OF REFERENCES CITED BY APPLICANT(S) (This secretal shooth if necessary)  FRING DATE 31 October 1987  U.S. PATENT DOCUMENTS  U.S. PATENT DOCUMENTS  FRING DATE  PORSIGN PATENT DOCUMENTS  FRING DATE  FRING DATE  PORSIGN PATENT DOCUMENTS  FRING DATE				5045-56103US	CIP	08/960,577		
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OTHER DOCUMENTS   Conducting Author, Tate, Onto, Partitional Pages, Str.]  DOCUMENTS SUBMITTED UNDER MPEP § 724  JAN 0 4 2005  Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004) - Subject to Protective Order  Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version] - Subject to Protective Order  Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004) - Subject to Protective Order  Expert Report of Dr. Sergio Fazio Regarding U.S. Patent No. 6,676,967 (August 17, 2004) - Subject to Protective Order  Expert Report of Don W. Martens (February 6, 2004) [Redacted Version] - Subject to Protective Order  Expert Report of Don W. Martens Regarding U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version] - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version] - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 5,676,967 (August 18, 2004)								
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Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version]  - Subject to Protective Order  Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004)  - Subject to Protective Order  Expert Report of Dr. Sergio Fazio Regarding  U.S. Patent No. 6,676,967 (August 17, 2004)  - Subject to Protective Order  Expert Report of Don W. Martens (February 6, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Don W. Martens Regarding  U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson Regarding  U.S. Patent No. 6,676,967 (August 18, 2004)			į					
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Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version]  - Subject to Protective Order  Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004)  - Subject to Protective Order  Expert Report of Dr. Sergio Fazio Regarding  U.S. Patent No. 6,676,967 (August 17, 2004)  - Subject to Protective Order  Expert Report of Don W. Martens (February 6, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Don W. Martens Regarding  U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version]  - Subject to Protective Order  Expert Report of Dr. Joseph R. Robinson Regarding  U.S. Patent No. 6,676,967 (August 18, 2004)						774	-0	CIVED
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\*EXAMINER: Initial II reference considered, whether or not citation is in conformance with MPEP 80%; Draw line through citation if not in conformance and not considered.

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FORM PTO 1449 (modified)			ATTY BOCKET NO.	APPLICATION N	о.		
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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				S045-56103USCIP  APPLICANT Expends Contal, et al. RECEIVED			
	LISTOF	RFFFR	ENCES CITED BY APPLICANT(S)	FILING DATE 31 October 1997 JAN 0 4	2000	GROUP	
			several sheets if necessary)	OFFICE	2005	1615	
<u> </u>	<del></del>			OFFICE OF PARTITION Date, Perforent Pages, Edit	Tillion.	1010	
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	Expert Report of Frank M. Sacks, M.D. (August 20, 2004)						
			- Subject to Protective Order				
	1			Mary Ann Tucker, Esq. (April 2, 2004)			
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L. Channavajjala

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FORM PTO 1449 (modific	ed)	ATTY DOCKET NO.	APPLICATION NO.	
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	OTHER DOCUMENT(S)	including Author, Title, Date, Partinent Pages, Etc.)		
DOCUMENTS SU		BMITTED UNDER MPEP § 7	724	e?h=
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Sample Kos Clinical Trial Investigator's Statement - Subject to Protective Order				
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	OTHER DOCUMENT(S) (	notuding Author, Title, Oats, Parlinera Pages, Ex	)	manus des Dadinesta	
<b>)</b>	Carl J. Lavie, et al., Marked with "Isolated" Very Low Lev	Benefit with Sustained-Releasels of High-Density Lipoprotein	e Niacin The n Cholestero	rapy in Fatients I and Coronary	
	Artery Disease, Am. J. Card	iol. 1992:69:1083-1085			
	_	0 and 2002 editions of the Phy		1	
		611, 856, 1189, 1919, 1 <mark>920, 2</mark> 49	11 and 2492)		
	2000 edition (pp. 1519-			<b></b> ,	
	2002 edition (pp. 1846-	.1820)		•	
	Niacin: Double-edged Sword	for Lowering Cholesterol, Tu	fts Universit	y Diet &	
	Nutritional Letter (Tufts Ur	niv., Boston, MA), August 199	4, Vol. 12, is:	rue 6	
	Larsen, ML and Illingworth, DR, Drug Treatment of Dyslipoproteinemia, Med Clin				
	Am., 78:225-245 (1994)	·			
	Lavle, Letter to Editor, JAN	/A 1994; 272:513-515			
	Keenan, Letter to Editor, Ja	AMA 1994; 272:513-515			
	Shields & Beckmann, Letter	r to Editor, JAMA 1994; 272:	513-515		
	Thomas N. Tozer, Clinical I at Chapter 9, p. 120	Pharmacokinetics Concepts as	d Application	ons (3d ed. 1995)	
	at Cuapter 7, p. 120				
	Excerpts from the 1995 United States Pharmacopeia (pp. iii-vi, 1080-1082, 1793-1795 1940-1944)				
	Morgan & Capuzzi Abstract, Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin, Clinical Pharmacology & Therapeutics (February 1996)				
	Manney & Comment Anti-la	Treatment Effect of Niaspan,	a Controlled	nolonse Nincin in	
	Morgan & Capuzzi Article, Patients With Hypercholeste Pharmacol. Therapeut. 1(3)	rolemia: A Placebo-controlled	<i>a Controlled</i> <i>Trial</i> , J. Car	diovasc.	
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FORM PTO 1448 (modified)		)	ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/980,577			
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			APPLICANT Expendo Cefell, et el.				
	LIST OF		RENCES CITED BY APPLICANT(S) - enveral ehoets if necessary)	FRING DATE 31 October 1997	4 2005	1615	
			OTHER DOCUMENT(S) (1	metuding Author, Title, Date, Police Con	PETTYASIA		
A	·/		Capuzzi DM, et al., Efficacy Long-Term Study, Am J Car	and Safety of An Extended-Rerdiol. 1998;82:74U-81U	dease Milein	(Niaspan): A	
			Guyton JR, Advances in Dys 82(12A): 85U-86U	slipidemia: Discussion Session	II, Am J Ca	rdiol, 1998:	
			Knopp RH, et al., Equivalen Once-a-Night Versus Plain N 47:1097-1104 (1998)	nt Efficacy of a Time-Release F Viacin in the Management of E	orm of Niaci Typerlipidemi	in (Niaspan) Given ia, Metabolism	
			American Diabetes Associat Diabetes Care 21:179-182, 1	tion: Management of Dyslipide 998	mla in Adult	s with Diabetes,	
			Elam MB, et al., Effect of No in Patients With Diabetes and	lacin on Lipid and Lipoprotein d Peripheral Arterial Disease, i	Levels and ( JAMA: 2000	Hycemic Control ; 284:1263-1270	
			(ALP; Small, Dense LDL, H.	vs. Niaspan (NS) Treatment of DL2, HDLc and Triglycerides): A268 at 1114-P (June 2000)	the Atheroge and Lp(a) in	nic Lipid Profile Diabetic Patients	
			2001 NCEP Report at VI-11	, Table VI.2-3			
Wang, W. et al., Effect of N Lipoprotein-Triglyceride Pri (2001)				icotinic Acid Administration on eduction, Am J Physiol Endoca	<i>Hepatic Ver</i> rinol Metab.,	y Low Density 280:E540-E547 	
			Smith SC, et al., AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update. AHA/ACC Scientific Statement, 1577-79				
	V		Tavintharan S and Kashyaj Reports 2001; 3:74-82	p M, The Benefits of Niacin in	Atherosclero	sis, Curr Athero.	
EXAMIN	ŒR	L	· Channavayor	DATE CONSIDERED	12/29/	5	
			J		I = I		

FORM PTO 1449 (#	nodiled)	ATTY DOCKET NO.	APPLICATION NO.			
		5045-56103USCIP	08/960,577			
	U.S. DEPARTMENT OF COMMERCE PAYENT AND TRADEMARK OFFICE	APPLICANT Euganio Cefati, et al.	RECEIVED			
LISTOF	REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)	FILING DATE 31 October 1997 J	AN 0 4 2005 GRO	-		
		OFFIC	E OF PETITIONS	15		
		including Author, Tille, Date, Perlinent Peges, b Injury: Leading Reason for L	mia Pamavale	<del></del> :		
A		r Magazione, May-June 2001	•	<i>i</i> .		
	Grundy SM, et al., Efficacy, Treatment of Dyslipidemia A 1568-1576	, Safety, and Tolerability of O Issociated with Type 2 Diabete	nce-Daily Niacin fa s. Arch Intern Me	or the d. 2002; 162:		
	American Diabetes Associa Diabetes Care 25:S74-S77,	tion: Management of Dyslipid 2002	lemia in Adults with 	h Diabetes,		
	Pan J, et al., Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabete Diabetes, Obesity and Metabolism 4:255-261 (2002)					
		ase Niacin Treatment of the A Metabolism 51:1120-1127 (20		rofile and		
	Meyers CD, et al., Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia, Ann Intern Med. 2003; 139:996-1002					
		CDER Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (March 2003)				
American Diabetes Association: Dyslipidemia Management in Adults with Diabetes Diabetes Care 27:S68-S71, 2004						
EXAMENER	- Channary Jal	DATE CONSIDERED 13	429/15	•		
Form #62			7 7	۲ 		